

## TWO-COMPARTMENT REDUCED VOLUME INFUSION PUMP

## BACKGROUND OF THE INVENTION

## 1. Field of the Invention

This invention relates to an infusion pump apparatus and method wherein small amounts of concentrated medication are mixed and diluted with a carrier prior to being released into the patient. The use of a concentrated medication which is diluted will reduce the required size of the pump and the frequency of a patient's refill visits.

## 2. Discussion of the Related Art

Implantable access ports and drug infusion pumps are well known in the art. For example, U.S. Patent No. 5,792,104 to Speckman et al. and U.S. Patent No. 5,833,654 to Powers et al. both disclose dual reservoir access ports. However, the ports of both Speckman and Powers are designed so that the contents of the reservoirs are never mixed, either internal or external to the ports. Both Speckman and Powers disclose attachment means and dual lumen catheters that are designed to keep the contents of the reservoirs separate until the catheter discharges into the patient. Thus, neither Speckman nor Powers allows for the contents of the reservoirs to be mixed prior to discharge to the patient.

Tucker et al. in U.S. Patent Nos. 4,193,397 and 4,258,711 (hereinafter "Tucker") disclose a dual reservoir implantable pump with an accumulator. Tucker further discloses a basal reservoir containing medication of a certain dosage and a smaller bolus reservoir containing high concentrate medication. The basal reservoir discharges medication to the patient at a specified rate. The basal reservoir discharges the high concentration of medication to a smaller accumulator and, at a specified time, the accumulator discharges the bolus dose into the basal medication discharge. However, Tucker's bolus dose is never mixed and diluted with the basal dose. The bolus dose is sent as a short 'burst' of medication at timed or triggered intervals. Additionally, both the basal and the bolus reservoirs contain medication that must be refilled by a doctor.

Thus, there is a need in the art for an implantable infusion device that mixes and dilutes a non-medication carrier with concentrated medication to reduce the size of the device. Additionally, diluting a concentrated medication with a carrier allows a patient to refill his/her own carrier reservoir multiple times before the medication reservoir requires refilling. This reduces the number of times a patient must visit a doctor to refill the medication reservoir.

## **SUMMARY OF THE INVENTION**

An implantable infusion apparatus has a medication reservoir for storing a medication and a carrier reservoir for storing a carrier. The entire apparatus, including both reservoirs, is typically located in a single housing. The housing can be made of stainless steel, titanium, or any other strong corrosion resistant material. The reservoirs are typically made in the form of a bellows that expands and contracts with the discharge and replenishment of the

liquid inside. The medication reservoir and the carrier reservoir are accessed through a medication access port and a carrier access port, respectively. The access ports are covered with a medication compound septum and a carrier compound septum, respectively. Both compound septa are formed from elastomeric, needle-penetrable, self-sealing material that enables needles to access the reservoirs. Additionally, access to the reservoirs can be gained through any number of valve, needle, and needle stop configurations as known in the art. Further, tactile ridges can be formed on the housing around the access ports to allow a doctor, nurse, or patient to locate the access ports by palpating the skin. Once the tactile ridges are located, it is immediately known where the medication and carrier compound septa are located below the skin. The placement and shape of the ridges are well known by those of skill in the art.

The carrier reservoir is larger and thus holds a larger volume than the medication reservoir. To reduce the size of the implantable infusion pump apparatus, the medication is highly concentrated to many times the dosage required. The concentrated medication is then diluted with the carrier to the proper dose, before it is discharged into the patient. The carrier is typically saline or other sterile liquid carrier. The carrier reservoir can be about 4 to about 5 times the size as the medication reservoir.

## **BRIEF DESCRIPTION OF THE DRAWINGS**

The above and still further objects, features and advantages of the present invention will become apparent upon consideration of the following detailed description of a specific embodiment thereof, especially when taken in conjunction with the accompanying

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drawings wherein like reference numerals in the various figures are utilized to designate like components, and wherein:

Figure 1 is a top view of the implantable infusion apparatus of the present invention;

Figure 2 is a partial cut-away view of the pump of along line 2 of Figure 3;

Figure 3 is a is a cross-section along line 3-3 of Figure 1;

Figure 4A is a top view of a microfluidic chip;

Figure 4B is a cross-sectional view along line 4B-4B of Figure 4A;

Figure 4C is a top view of an alternate embodiment of the microfluidic chip;

Figure 5 is a magnified view of one embodiment of the flow paths of the present invention;

Figure 6 is a magnified view of another flow path embodiment of the present invention;

Figure 7 is a magnified view of a restricted flow path embodiment of the present invention;

Figure 8 is a magnified view of the medication flow selector of the present invention;

Figure 9 is a magnified view of another flow path of the present invention;

Figure 10 is a schematic flow diagram illustrating a flow path of the present invention;

Figure 11 is a schematic flow diagram illustrating another flow path of the present invention;

Figure 12 is a flow chart illustrating a method of infusing medication according to the present invention;

Figure 13 is a flow chart illustrating another method of infusing medication according to the present invention; and

Figure 14 is a flow chart illustrating another embodiment for infusing medication.

### **DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT**

Referring now to Figures 1 and 2, an implantable infusion apparatus 100 in accordance with the present invention is illustrated. Figure 2 illustrates a medication reservoir 102 for storing a medication 104 and a carrier reservoir 106 for storing a carrier 108. The entire apparatus, including both reservoirs, is typically located in a housing 110. Housing 110 can be made of stainless steel, titanium, or any other strong corrosion-resistant, biocompatible material. The reservoirs are typically in the form of a bellows 112 (Figure 3) that expands and contracts with the discharge and replenishment of the liquid inside. Figure 1 illustrates that medication reservoir 102 and carrier reservoir 106 are accessed through a medication access port 114 and a carrier access port 116, respectively. Access ports 114, 116 are covered with a medication compound septum 118 and a carrier compound septum 120, respectively. Both compound septa 118, 120 are formed from elastomeric, needle-penetrable, self-sealing material that enables needles to access the reservoirs. Additionally, access to reservoirs 102, 106 can be gained through any number of valve, needle, and needle stop configurations as known in the art. Further, tactile ridges 122 can be formed on the housing around access ports 114, 116 to

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allow a doctor, nurse, or patient to locate access ports 114, 116 by palpating the skin. Once tactile ridges 122 are located, it is immediately known where medication compound septum 118 and carrier compound septum 120 are located below the skin. The placement and shape of the ridges are well known by those of skill in the art.

Figures 2 and 3 illustrate that carrier reservoir 106 is larger than medication reservoir 102. To reduce the size of implantable infusion apparatus 100, medication 104 is highly concentrated to many times the dosage required. Concentrated medication 104 is then diluted with carrier 108 before it is discharged to the patient. Carrier 108 is typically saline or other sterile liquid carrier. Carrier reservoir 106 can be about 4 to about 5 times the size as medication reservoir 102. For example, carrier reservoir 106 can hold 20 ml and the medication can be about 4 ml or about 5 ml and the above arrangement can replace one 40 ml reservoir.

In addition to reducing the size of the implantable infusion apparatus, the invention can reduce or shorten the number or length of a patient's doctor visits. Typically, only a doctor can refill medication reservoir 102. But, because medication 104 is highly concentrated and then diluted with carrier 108, the doctor will not be required to fill medication reservoir 102 as often. Carrier reservoir 106 is only filled with a non-medication substance. Since carrier 108 is not a medication, either the patient at home, or a nurse can refill carrier reservoir 106. In one embodiment, carrier compound septum 120 is larger and/or differently shaped than the medication compound septum 118 to assist the patient in locating carrier reservoir 106. An alternate embodiment can provide a single access port for both reservoirs wherein only a particular type of needle (e.g. by length or location of the discharge

orifice) can access each of the reservoirs. The above safeguards can allow a patient to safely refill carrier reservoir 106. The location of access ports 114, 116 with respect to pump housing 110 can also assist the patient/nurse/doctor in distinguishing between carrier access port 116 and medication access port 114. For example, medication access port 114 can be disposed in the center of housing 110 and carrier access port 116 can be disposed along housing's 110 perimeter.

A mixing chamber 124 is included to thoroughly mix and dilute medication 104 with carrier 108. Mixing chamber 124 must allow for full dilution and mixing of carrier 108 with medication 104 or the patient will receive an improper dose. One embodiment, as illustrated in Figures 4A and 4B, uses a microfluidic chip 128 to mix the two substances. Microfluidic chip 128 can have a medication input 130 and a carrier input 132 and capillary pathway 134 is configured in a serpentine pattern. The capillary pathway 134 can include convolutions in vertical and horizontal planes to the direction of flow. The convolutions act to allow medication 104 sufficient contact time with carrier 108 to allow for thorough mixing. Examples of microfluidic mixing chips include U.S. Patent Publication No. 2001/0048900, to Bardell et al.; U.S. Patent Publication No. 2003/0040105 to Sklar et al.; and U.S. Patent Publication No. 2003/0133358 to Karp. Other microfluidic mixing chips and mixing chambers to allow for thorough mixing are known to those of skill in the art.

One key to the mixing process is controlling the flow of both medication 104 and carrier 108 from reservoirs 102, 106 to mixing chamber 124. The flow rate can be controlled in numerous ways described below.

Referring now to Figures 5 through 9, a medication flow path 136 fluidly connects medication reservoir 102 to mixing chamber 124 and a carrier flow path 138 fluidly connects carrier reservoir 106 to mixing chamber 124. The flow paths can simply act as conduits between the reservoirs and the mixing chamber. Figure 5 illustrates one embodiment that alters the physical properties of medication flow path 136 so it is less restrictive than carrier flow path 138. Conversely, Figure 6 illustrates that medication flow path 136 is more restrictive than carrier flow path 138. The restrictive nature of a flow path is a factor in determining the flow rate of the fluid inside the path. For example, as illustrated in Figure 5, medication flow path 136 can be designed with a larger diameter A than a smaller diameter B of carrier flow path 138. Figure 6 illustrates that larger diameter A of carrier flow path 138 can be larger than smaller diameter B of medication flow path 136. The restrictions in the flow path can also be built into microfluidic chip 128, after inputs 130, 132, and before mixing chamber 124. Figure 4C illustrates a medication reduced diameter section 131, internal to microfluidic chip 128 that can act as the restriction to flow. Alternately, a carrier reduced diameter section 133 can also be disposed internal to microfluidic chip 128 to restrict the flow of carrier 108. Figure 4C illustrates both medication and carrier reduced diameter sections 131, 133, however, the reduced diameter sections can be used together or only one section can be restricted.

Additional embodiments, as illustrated in Figures 7 through 9, dispose either a medication flow restrictor 140 in medication flow path 136 to restrict the flow of medication 104 between medication reservoir 102 and mixing chamber 124; a carrier flow restrictor 142 in carrier flow path 138 to restrict the flow of carrier 108 between carrier reservoir 106 and



mixing chamber 124; or both flow restrictors 140, 142 can be included in the same apparatus, as illustrated in Figure 7. Flow restrictors 140, 142 can be physical changes to flow paths 136, 138 or microfluidic chips (not illustrated), depending on the configuration and flow rate required. As above, either flow restrictor 140, 142 can be more or less restrictive than the other.

Referring to Figure 8, a medication pump system 144 is used to discharge medication 104 to mixing chamber 124 and a carrier pump system 146 is used to discharge carrier 108 to mixing chamber 124. Medication pump system 144 has a medication discharge rate  $Q_m$  and carrier pump system 146 has a carrier discharge rate  $Q_c$ . As above, to properly control the mixing of medication 104 with carrier 108, the proper flows must be determined so the proper amount of medication 104 is diluted with the proper amount of carrier 108, depending on the dose to be administered to the patient. Discharge rates  $Q_m$ ,  $Q_c$  can be configured in many ways, for example, medication discharge rate  $Q_m$  can equal carrier discharge rate  $Q_c$  and the flow can be restricted down stream of the pump by either flow paths 136, 138 or flow restrictors 140, 142. Alternately, medication discharge rate  $Q_m$  can be greater than or less than carrier discharge rate  $Q_c$  or any combination of flow paths 136, 138, flow restrictors 140, 142 and discharge rates  $Q_m$ ,  $Q_c$  can be used to control the flow of both carrier 108 and medication 104.

Pump systems 144, 146 can be any pumping system known to those of skill in the art, including a power cell 113, 115 associated with the medication and the carrier reservoirs, respectively. Power cells 113, 115 can be a two-phase fluid power cell, where the fluid in the power cell vaporizes at physiological temperatures. The gas formed from the





carrier but the medication and/or carrier flow rate can be adjusted by a doctor to alter the flow rate of the constant flow.

Figures 10 and 11 are schematic diagrams illustrating typical embodiments for the present invention. Figure 10 schematically illustrates medication access port 114 in-line with medication reservoir 102. Medication flow path 136 fluidly connects medication reservoir 102 to mixing chamber 124 via medication flow restrictor 140. Carrier access port 116 is fluidly connected to carrier reservoir 106 and carrier flow path 138 fluidly connects carrier reservoir 106 to mixing chamber 124 via carrier flow restrictor 142. Further, bolus port 150 is disposed in the flow path between mixing chamber 124 and outlet 148 to permit the injection of a bolus dose. Figure 11 illustrates another embodiment wherein medication flow selector 154 is located in the flow path between medication flow restrictor 140 and mixing chamber 124 to allow additional control of medication discharge rate  $Q_m$ .

Figure 12 illustrates a method of infusing medication including storing a medication in a medication reservoir (step 200) and storing a carrier in a carrier reservoir (step 202). The carrier reservoir is sized larger than the medication reservoir. Approximately simultaneously, the medication is discharged to a mixing chamber (step 204) and the carrier is discharged to the mixing chamber (step 206). Once in the mixing chamber, the medication is mixed with the carrier to dilute it (step 208); and then the diluted medication/carrier mixture is discharged (step 210). As an additional step, a bolus dosage may be introduced into the diluted medication/carrier mixture prior to discharging the diluted medication/carrier mixture (step 212).

Another embodiment can restrict the discharge of the medication (step 214), restrict the discharge of the carrier (step 216) or restrict both. When both the medication and the carrier are restricted, the discharge of the medication can be restricted more than the



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